

REMARKS

This paper is responsive to the Office Action mailed May 29, 2008 and to the Notice mailed December 12, 2008. Applicant requests that the Examiner replace the Remarks filed on August 29, 2008, with the instant Remarks and further that the Examiner enter the claim amendments previously filed on August 29, 2008. Therefore, with this submission, claims 1-5, 7, 9-11, 17-18, and 26 have been amended. Claims 1-59 are pending; claims 1-5, 9-11, 14, 15, 18-20, and 53-55 are under consideration; and claims 6-8, 12, 13, 16, 17, 21-52, and 56-59 are withdrawn, subject to rejoinder at the Examiner's discretion.

Support for the instant amendment can be found throughout the specification as filed, e.g., at page 19, last paragraph. Reconsideration and withdrawal of the rejections made in the above-referenced Office Action are respectfully requested in view of the following remarks.

Information Disclosure Statement

Applicant thanks the Examiner for acknowledgement of receipt of the Information Disclosure Statement filed February 21, 2008. Applicant also thanks the Examiner for considering all of the information listed in said Information Disclosure Statement (IDS), and for indicating such consideration with an electronic signature as well as an initialed notation at the bottom of the document.

Applicant notes that the Office Action mailed May 29, 2008 does not acknowledge receipt of the second supplemental IDS filed on May 27, 2008; the Office Action and the IDS appear to have crossed in the mail. Applicant has confirmed that the IDS was received by the Patent Office, and that the documents listed therein have been scanned and are available for the Examiner to consider with our response to this non-final Office Action. Accordingly, the

Examiner is respectfully requested to consider the materials submitted on May 27, 2008 and to indicate such consideration by returning a signed and initialed copy of the PTO-1449 Form with the next official communication.

Claim Rejections – 35 U.S.C. § 103(a)

The Office Action rejects claims 1-5, 9-11, 18-20, 53 and 54 under 35 U.S.C. § 103(a) as allegedly unpatentable over SCHALLER (U.S. Patent 6,254,947) in view of TERRY (U.S. Patent Application Pub. No. 2005/0064176 A1). In particular, the Office Action states that SCHALLER teaches a multi-layer medical glove article having an antifriction layer, an elastomeric base layer including an internal and an external surface, and an anti-friction layer comprised of a polymeric material with raised areas and recesses that extend through the anti-friction layer to the base layer. The Office Action also states that SCHALLER is silent on the percentage range of recesses (20-95%) that extend through to the base layer, but that “Fig. 1 shows the majority of recesses extend to the base layer, thus it is the opinion of the Examiner that the reference reads on the instant range” (see page 3, first paragraph of the Office Action mailed May 29, 2008).

The Office Action also states that SCHALLER does not teach the use of particles within the article. For this missing feature, the Office relies upon TERRY, which allegedly teaches the use of antimicrobial particles in a coating that is applied to a substrate or device, wherein the substrate can be a glove or condom and the particles can be applied into one layer while keeping a second layer particle free.

The Office Action also asserts that one of ordinary skill in the art would have been motivated to combine the teachings of SCHALLER and TERRY because of “the beneficial

effects of incorporating an active pharmaceutical into a glove or condom to prevent the spread of microbes, as taught by TERRY” (see the Office Action at page 4, first paragraph).

In response, Applicant submits that the claimed subject matter is not unpatentable over SCHALLER in view of TERRY. In particular, Applicant submits that SCHALLER and/or TERRY, either alone or in combination, do not disclose or suggest the instant invention because even when combined, SCHALLER and TERRY do not disclose a “[m]ulti-layered prophylactic article comprising:

(i) an elastomeric base layer including an internal and an external surface and

(ii) an anti-friction layer comprising:

(a) a polymeric material with an internal surface and an external surface facing the internal surface of the base layer; and

(b) regularly recurring raised areas or recesses of an irregular shape, produced by rapidly removing liquid from the anti-friction layer, such that a lower limit of 20% and an upper limit of 95% of the total number of recesses extends through the entire thickness of the anti-friction layer; and

(iii) microcapsules with a diameter having an upper limit of 500 μm and a lower limit of 10 μm and which contain at least one active substance and/or dye inside and positioned in at least one of the following: between the base layer and the anti-friction layer or a part region thereof, in the anti-friction layer or a part region thereof, on the internal surface of the anti-friction layer or a part region thereof, or within a layer incorporating the at least one active substance and/or dye in at least a part region between the base layer and the anti-friction layer.”

For example, neither SCHALLER nor TERRY disclose active substances enclosed *inside* particles, especially microparticles. In particular, TERRY discloses only the direct use

antimicrobial particles themselves, not the use of particles which contain at least one active substance and/or dye *inside*. Furthermore, SCHALLER does not compensate for this deficiency.

In addition, and as conceded by the Examiner, SCHALLER does not teach a percentage range of recesses that extends through the entire thickness of the anti-friction layer, much less raised areas or recesses of an irregular shape, such that a lower limit of 20% and an upper limit of 95% of the total number of recesses extends through the entire thickness of the anti-friction layer. Moreover, Applicants submit that TERRY fails to compensate for this deficiency.

Therefore, even if *arguendo* one of ordinary skill in the art were motivated to combine the cited documents, SCHALLER and TERRY fail to disclose or fairly suggest a “[m]ulti-layered prophylactic article comprising:

- (i) an elastomeric base layer including an internal and an external surface and

- (ii) an anti-friction layer comprising:

- (a) a polymeric material with an internal surface and an external surface facing the internal surface of the base layer; and

- (b) regularly recurring raised areas or recesses of an irregular shape, produced by rapidly removing liquid from the anti-friction layer, such that a lower limit of 20% and an upper limit of 95% of the total number of recesses extends through the entire thickness of the anti-friction layer; and

- (iii) microcapsules with a diameter having an upper limit of 500 μm and a lower limit of 10 μm and which contain at least one active substance and/or dye inside and positioned in at least one of the following: between the base layer and the anti-friction layer or a part region thereof, in the anti-friction layer or a part region thereof, on the internal surface of the anti-

friction layer or a part region thereof, or within a layer incorporating the at least one active substance and/or dye in at least a part region between the base layer and the anti-friction layer.”

For at least the foregoing reasons, Applicant submits that SCHALLER and TERRY, either alone or in combination, do not disclose or suggest the instant invention, and respectfully requests withdrawal of the rejection under 35 U.S.C. § 103.

The Office Action also rejects claims 1, 14, 15 and 55 under 35 U.S.C. 103(a) as allegedly unpatentable over SCHALLER in view of TERRY and in further view of HAMANN (U.S. Patent Application Pub. No. 2004/0091504 A1). In particular, the Office Action states that SCHALLER teaches recesses and raised areas in an anti-friction layer of a multi-layer medical glove, and that TERRY teaches the use of particles in and on a medical glove or condom. However, the Office further states that SCHALLER does not teach the use of plant extracts or vitamins in the article. For this missing feature, the Office relies upon HAMANN, which allegedly teaches a multilayer prophylactic article or glove wherein a plant extract is incorporated into an elastomer layer of the article or glove.

The Office Action also asserts that one of ordinary skill in the art would have been motivated to combine the teachings of SCHALLER and TERRY with those of HAMANN because of “the beneficial effect anti-microbials and vitamins have on anti-aging (such as moisturizing) and microbe control, as taught by HAMANN” (see page 5, first full paragraph of the Office Action mailed May 29, 2008).

In response, Applicant submits that the claimed subject matter is not unpatentable over SCHALLER in view of TERRY, and further in view of HAMANN. In particular, Applicant submits that SCHALLER, TERRY and/or HAMANN, either alone or in combination, do not

disclose or suggest the instant invention at least for the reasons expressed above with regard to SCHALLER and TERRY.

With regard to HAMANN in particular, Applicant submits that HAMANN fails to disclose active substances enclosed *inside* particles, especially microparticles. Furthermore, neither TERRY nor SCHALLER compensate for this deficiency. In addition, and as conceded by the Examiner with regard to SCHALLER, none of the cited documents teach a percentage range of recesses that extends through the entire thickness of the anti-friction layer, much less raised areas or recesses of an irregular shape, such that a lower limit of 20% and an upper limit of 95% of the total number of recesses extends through the entire thickness of the anti-friction layer.

Therefore, even if *arguendo*, one of ordinary skill in the art were motivated to combine the cited documents, SCHALLER, TERRY, and HAMANN fail to disclose or fairly suggest a “[m]ulti-layered prophylactic article comprising:

- (i) an elastomeric base layer including an internal and an external surface and

- (ii) an anti-friction layer comprising:

- (a) a polymeric material with an internal surface and an external surface

- facing the internal surface of the base layer; and

- (b) regularly recurring raised areas or recesses of an irregular shape,

- produced by rapidly removing liquid from the anti-friction layer, such that a lower limit of 20% and an upper limit of 95% of the total number of recesses extends through the entire thickness of the anti-friction layer; and

- (iii) microcapsules with a diameter having an upper limit of 500 μm and a lower limit of 10 μm and which contain at least one active substance and/or dye inside and positioned

in at least one of the following: between the base layer and the anti-friction layer or a part region thereof, in the anti-friction layer or a part region thereof, on the internal surface of the anti-friction layer or a part region thereof, or within a layer incorporating the at least one active substance and/or dye in at least a part region between the base layer and the anti-friction layer.” SCHALLER, TERRY, and HAMANN also fail to disclose or fairly suggest such a prophylactic article wherein the active substance is selected from a group consisting of vitamins and plant extracts.

For at least the foregoing reasons, Applicant submits that SCHALLER, TERRY, and/or HAMANN, either alone or in combination, do not disclose or suggest the instant invention, and respectfully requests withdrawal of the rejection under 35 U.S.C. § 103.

Claim Rejections – Obvious Type Double Patenting

The Office Action rejects claims 1, 9-11, 18, and 53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 16-18, and 30 over U.S. Patent Application No. 11/621,828, which published as US Patent Application Publication No. 2008/0040834 A1.

In response, Applicants respectfully submit that the claims of the present application are not obvious in view of the claims of the co-pending application. In particular, Applicants submit that claims 1, 9-11, and 18 of the instant application are drawn in part to a “[m]ultilayered prophylactic article comprising...(iii) microcapsules with a diameter having an upper limit of 500 μm and a lower limit of 10 μm ...”. Similarly, claim 53 of the instant application is drawn in part to a “[m]ulti-layered prophylactic medical glove comprising...(iii) particles with a diameter having an upper limit of 500 μm and a lower limit of 10 μm ...”. However, claims 1, 3, and 16-

18 of co-pending U.S. Patent Application No. 11/621,828 are drawn in part to a “[m]ultilayered prophylactic article comprising...microcapsules contained in an anti-friction layer, and at least 90% of the microcapsules comprise singular capsules having a diameter of less than 10 μm ...”. Moreover claim 30 of co-pending U.S. Patent Application No. 11/621,828 recites “[a] prophylactic article comprising the composition according to claim 2 as an antifriction layer,” and claim 24 is drawn to a “[c]omposition for production of an anti-friction layer of a prophylactic article, comprising a mixture of water, polyurethane and microcapsules, and 90% of the microcapsules have a diameter of less than 10 μm .” Thus, the rejected claims of the instant application recite microcapsule diameter ranges which are non-overlapping with and not suggested by the microcapsule diameter ranges recited in the co-pending application.

In addition, Applicant notes that claim 7 of co-pending U.S. Patent Application No. 11/621,828, from which claims 16-18 depend, is drawn to a “[p]rophylactic article according to claim 1, wherein the singular capsules are arranged as agglomerates” whereby the ease in putting on the article and/or the wet slipperiness can be improved through the increase in the surface roughness on the inside of the prophylactic article.

Based at least on the above, Applicant submits that instant claims 1, 9-11, 18, and 53 are not unpatentable over claims 1, 3, 16-18, and 30 over U.S. Patent Application No. 11/621,828, on the ground of nonstatutory obviousness-type double patenting, and respectfully request withdrawal of the rejection.

However, if the Examiner chooses to maintain the obviousness-type double patenting rejection, Applicants respectfully request, in accordance with MPEP 1504.06, that the Examiner allow the present application (the earlier filed application) to proceed to issuance, whereby an

obviousness-type double patenting rejection can be made (if appropriate) in the copending application.

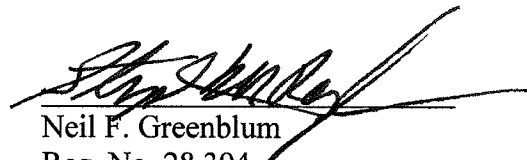
Conclusion

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow all the pending claims.

No additional fee is believed due at this time. If, however, any additional fee is necessary to ensure consideration of the submitted materials, the Patent and Trademark Office is hereby authorized to charge the same to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,
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